(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
3 October 2002 (03.10.2002)

PCT

(10) International Publication Number
WO 02/076317 A1

(51) International Patent Classification[7]: A61B 17/70, 17/80

(21) International Application Number: PCT/US02/09168

(22) International Filing Date: 27 March 2002 (27.03.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/279,157 27 March 2001 (27.03.2001) US

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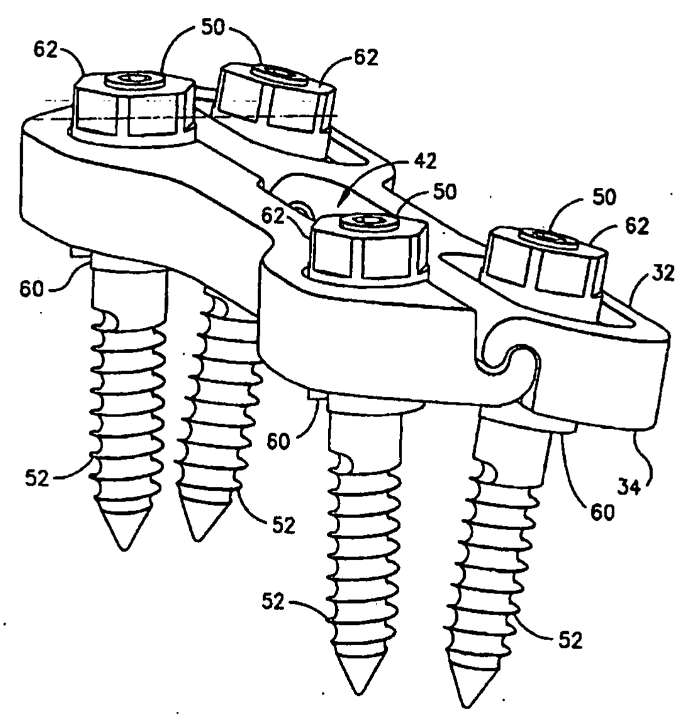
(81) Designated States (*national*): AU, CA, JP.

(84) Designated States (*regional*): European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR).

Published:
— *with international search report*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: HINGED ANTERIOR THORACIC/LUMBAR PLATE



(57) Abstract: An anterior thoracic/lumbar system comprising a thin plate and fasteners for securing the plate to vertebrae or other osseous material. The plate may be hinged along the central axis, with a pair of collinear holes on each portion of the plate. Each of the holes accommodates a bolt which is screwed into the vertebrae and secured to the plate using a nut.

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HINGED ANTERIOR THORACIC/LUMBAR PLATE

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims benefit from U.S. Provisional Patent Application Serial No. 60/279,157, filed March 27, 2001, which application is incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates generally to devices for use in spinal surgery, and, in particular, to a hinged anterior thoracic/lumbar plate which is implantable within a patient for stabilization of the spine.

2. Description of the Related Art

Eighty-five percent of the population will experience low back pain at some point. Fortunately, the majority of people recover from their back pain with a combination of benign neglect, rest, exercise, medication, physical therapy, or chiropractic care. A small percent of the population will suffer chronic low back pain. The cost of treatment of patients with spinal disorders plus the patient's lost productivity is estimated at 25 to 100 billion dollars annually.

Seven cervical (neck), 12 thoracic, and 5 lumbar (low back) vertebrae form the normal human spine. Intervertebral discs reside between adjacent vertebra with two exceptions. First, the articulation between the first two cervical vertebrae does not contain a disc. Second, a disc lies between the last lumbar vertebra and the sacrum (a portion of the pelvis).

Motion between vertebrae occurs through the disc and two facet joints. The disc lies in the front or anterior portion of the spine. The facet joints lie laterally on either side of the posterior portion of the spine. The osseous-disc combination of the spine coupled with ligaments, tendons, and muscles are essential for spine function. The spine allows movement (flexation, lateral bending, and rotation), supports the body, and protects the spinal cord and nerves.

The disc changes with aging. As a person ages the water content of the disc falls from approximately 85 percent at birth to 70 percent in the elderly. The ratio of chondroitin sulfate to keratin sulfate decreases with age. The ratio of chondroitin 6 sulfate to chondroitin 4 sulfate increases with age. The distinction between the annulus and the nucleus decreases with age. These changes are known as disc degeneration. Generally disc degeneration is painless.

Premature or accelerated disc degeneration is known as degenerative disc disease. A large portion of patients suffering from chronic low back pain is thought to have this condition. As the disc degenerates, the nucleus and annulus functions are compromised. The nucleus becomes thinner and less able to handle compression loads. The annulus fibers become redundant as the nucleus shrinks. The redundant annular fibers are less effective in controlling vertebral motion. The disc pathology can result in: 1) bulging of the annulus into the spinal cord or nerves; 2) narrowing of the space between the vertebrae where the nerves exit; 3) tears of the annulus as abnormal loads are transmitted to the annulus and the annulus is subjected to excessive motion between vertebrae; and 4) disc herniation or extrusion of the nucleus through complete annular tears. Disc herniation can also cause arthritis of the facet joints, which, in turn, may cause back pain.

The problems created by disc degeneration, facet arthritis, and other conditions such as spondylolysis, spondylolisthesis, scoliosis, fracture, tumor, or infection are frequently treated by spinal fusion. Such problems may include pain in the back or legs, nerve injury, risk of future nerve injury, or spinal deformity. The goal of spinal fusion is to successfully "grow" two or more vertebrae together. To achieve this, bone from the patient's body (spine or iliac crest) or from cadavers is grafted between vertebrae. Alternatively, bone graft substitutes, such as hydroxyapatite and bone morphogenetic protein, may be used. The bone graft is placed between the vertebrae in the disc space and/or over the posterior elements of the vertebrae (lamina and transverse processes). The surgeon scrapes the vertebrae to create bleeding. Blood flows into the bone graft. The scraped bone, blood clot (hematoma), and the bone graft simulates a fracture. As the patient heals, the "fracture" causes the vertebrae to be fused and heal together.

Spinal instrumentation may be placed onto or into the spine to immobilize the vertebrae that are going to be fused. Immobilization leads to a higher fusion rate and speeds a patient's recovery by eliminating movement. The use of spinal fixation plates or rods for correction of spinal deformities and for fusion of vertebrae is well known. Typically, a rigid plate is positioned to span bones or bone segments that need to be immobilized with respect to one another. Bone screws may be used to fasten the plate to the bones. Spinal plating systems are commonly used to correct problems in the lumbar and cervical portions of the spine, and are often installed posterior or anterior to the spine.

One technique of treating these disorders is known as surgical arthrodesis of the spine. This can be accomplished by removing the intervertebral disk and replacing it with bone and immobilizing the spine to allow space to connect the

adjoining vertebral bodies together. The stabilization of the vertebrae to allow fusion is often assisted by a surgically implanted device to hold the vertebral bodies in proper alignment and allow the bone to heal, much like placing a cast on a fractured bone. Such techniques have been effectively used to treat the above described conditions and in most cases are effective at reducing the patient's pain and preventing neurologic loss of function.

Several types of anterior spinal fixation devices are currently in use. One technique involves placement of screws completely through the vertebral body, called bicortical purchase. The screws are placed through a titanium plate but are not attached to the plate. This device is difficult to place, and over-penetration of the screws can result in damage to the spinal cord. The screws can back out of the plate into the surrounding tissues as they do not fix to the plate. Several newer generation devices have used a unicortical purchase of the bone, and in some fashion locking the screw to the plate to provide stability and secure the screw from backout. Problems have resulted from over rigid fixation and stress shielding, resulting in nonunion of the bony fusion, chronic micromotion during healing, resulting in stress fracture of the fixation device at either the screw to the plate resulting in screw backout, or inadequate fixation strength and resultant collapse of the graft and angulation of the spine.

Another technique involves formation of a medical construct using surgical rods and connectors. Such systems include a pair of rods which are placed on opposite sides of the portion of the spine which is intended to be fused. Pedicle, lateral, and oblique mounting means are used to secure the rods relative to the desired portion of the spine which will be fused by the fixation system. However, this

construct extends outwardly further than a plate/screw system, potentially affecting the surrounding muscle, and causing pain to the patient.

Plates and screws are often placed onto the anteriolateral portion of the spine to facilitate spinal fusion. . Generally, they are placed across one or two disc spaces in the treatment of fractures and tumors. Most of the present systems use screws with nuts for the posterior portion of the vertebrae. The screws with nuts are commonly called bolts by those skilled in this art. Screws, without nuts, are placed through the anterior portion of the plate. The posterior bolts are generally thought to rigidly fix the plate to the screws. Some surgeons believe that the rigid bolt/plate construct provides more spinal stability. However, while screws without nuts are easier to insert, they also are known to back out, causing potential failure of the fusion. Devices have been devised to hold the screws within the plate. It is believed that there are no systems in the marketplace which uses an all bolt construct.

A typical device which is used for spinal fixation is taught in U.S. Patent No. 4,611,581. This device consists of a simple plate having a series of openings for receiving threaded portions of force transmitting members which securely lock in a part of the bone of the vertebra in which they are mounted and a threaded portion which projects outwardly from the vertebrae. The vertebra is pulled into the desired relationship with adjacent vertebrae by tightening a nut on the outwardly projecting end portion of the force transmitting member.

Another typical device used is shown in U.S. Patent No. 6,306,136. This patent discloses an implant which is used particularly as an anterior cervical plate, having a solid plate consisting of two sliding parts, each of which has holes for anchoring screws in two adjacent vertebrae. The sliding parts are provided with a screw and slot for limiting the sliding travel between the parts.

Another vertebrae connecting plate is taught in U.S. Patent No. 5,147,361. This plate has a small thickness, and uses set screws which are screw engaged in threaded holes within the connecting plate to prevent any loosening of the screws within the plate.

SUMMARY OF THE INVENTION

It is therefore an object of the present invention to provide a plate system for spinal surgery, which has a low profile and comfortably fits a patient's anatomy.

It is a further object of the present invention to provide a plate system which is easily implanted within a patient.

It is a further object of the present invention to provide a plate system which is easily positioned and establishes a secure connection between vertebrae.

It is still a further object of the present invention to provide a plate system that is top loading and top tightening.

It is a still further object of the present invention to provide a plate system which is easily adaptable to the lumbar/thoracic region of the spine.

These and other objects and advantages of the present invention will be readily apparent in the description that follows.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a lateral view of a prior art spinal plate installed in vertebrae of a spine;

FIG. 2 is an anterior to posterior view of the plate shown in FIG. 1;

FIG. 3 is an exploded lateral view of the plate and associated devices shown in FIG. 1;

FIG. 4 is an end view of the plate and devices of FIG. 3 in the assembled position;

FIG. 5 is a perspective partially assembled view of the spinal plate of the present invention along with C-rings;

FIG. 6 is another perspective partially assembled view of the system of FIG. 5 along with locking nuts;

FIG. 7 is a perspective view of the spinal plate system of FIG. 5 in its assembled position;

FIG. 8 is a lateral view of the plate system of the present invention with two bolts installed;

FIG. 9 is a lateral view of the plate system of the present invention during the installation of two C-rings;

FIG. 10 is a lateral view of the plate system of the present invention with the nut installed on the lower posterior bolt;

FIG. 11 is a lateral view of the plate system with the two posterior bolts installed;

FIG. 12 is a lateral view of the plate system with C-rings for the anterior bolts;

FIG. 13 is a lateral view of the plate system of the present invention completely installed;

FIG. 14 is a sectional view of the system shown in FIG. 13;

FIG. 15 is a fragmentary view of an anterior hole of plate of the present invention showing the beveled orientation through the plate;

FIG. 16 is a lateral view of the plate system having slotted holes on the anterior section of the plate;

FIG. 17 is a lateral view of an alternative embodiment of the plate system of the present invention;

FIG. 18 is a side view of the plate shown in FIG. 17 partly in phantom;

FIG. 19 is a cross-sectional view of the plate shown in FIG. 17;

FIG. 20 is a plan view of a plate of the present invention which is angled for use on a kyphotic spine;

FIG. 21 is a plan view of a plate of the present invention which is angled for use on a lordotic spine; and

FIG. 22 is a plan view of another embodiment of a spine plate according to the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIGS. 1-4 represent a common prior art method currently used for spinal stabilization. Referring now to FIGS. 1 and 2, there is shown a spinal plate 10 which has been placed across several vertebrae 12, 14. Plate 10 contains a series of openings 16 which are intended to receive bone anchoring hardware. As can be clearly seen in FIG. 1, two of openings 16 are positioned against vertebra 12, while two of openings 16 are positioned against vertebra 14. A bone graft 18 which replaced a vertebra is positioned between vertebrae 12, 14.

Most prior art spinal plate systems use a combination of screws and bolts to attach spinal plates to the posterior portion of the vertebrae. Referring again to FIG. 1, a pair of screws 20, having a threaded section 21, are installed through the anterior portion of plate 10, while a pair of bolts 22 are installed through the posterior portion of plate 10. Each bolt 22 consists of a lower threaded section 23 and an

upper threaded post 24 which is affixed in position by a nut 26. The threaded sections of 21, 23 of screws 20 and bolts 22 are anchored into the bone of vertebrae 12, 14. When placed within the spine, bolts 22 and screws 20 converge to resist pull-out, as can be clearly seen in FIG. 4. This combination is believed to provide more spinal stability, as bolts rigidly affix the spinal plate to the screws, which are much easier to insert in the procedure.

Most spinal plates available today use only screws, or the screw/bolt combination. In addition, as screws sometimes have a tendency to back out of the bone, devices are available to secure the screws in place.

Referring now to FIGS. 5-7, a hinged spinal plate system, generally designated at 30, which embodies the principles of the present invention, is shown. This system is ideally suited for use in the lumbar/thoracic portion of the spinal column.

Plate system 30 includes a thin plate 32 having two plate elements 32a, 32b which are removably coupled together along a hinged section 34. Element 32a, which contains generally rounded edges 35a, 35b and a cutaway section 35c has two generally circular through openings 36, which are positioned collinearly along element 32a. Element 32b also contains generally rounded edges 38a, 38b and a cutaway section 38c, and has two generally circular through openings 40 positioned collinearly along element 32b. Although openings 36, 40 are shown as circular in this embodiment, they may also consist of elongated slots. Cutaway sections 35c, 38c afford the surgeon a better view of the bone graft inserted between vertebrae, to insure that the bone graft is not projecting into the spinal cord or nerves. Plate 32 is generally constructed from an implant grade titanium alloy, such as Ti-6Al-4V, or possibly stainless steel ASTM F138.

Along hinged section 34 of plate system 30 there is an opening 42 formed by a cutout section 42a in element 32a and a cutout section 42b in element 32b. Opening 42 may be used if additional hardware is desired to increase the holding force of system 30 against the spine for greater stability, or to secure the bone graft.

A series of bolts 50 are inserted through openings 36, 40 to secure plate 32 to the vertebrae. Bolts 50 contain a lower threaded portion 52 for threadedly engaging holes which are drilled into the appropriate vertebrae of the spine, and an upper threaded portion 54 which extends through plate 32 when it is in its proper location against the spine.

A series of snap or C-rings 60 are used with bolts 50 to securely fasten plate 32 in its proper position. Snap or C-rings 60 are clipped onto upper threaded position 54 of bolts 50 after lower threaded portion 52 has been anchored within the appropriate vertebrae. Finally, a series of nuts 62 are threaded onto upper threaded portion 54 of bolts 50 to secure plate 32 in its proper position. It is possible that ordinary washers could be used in place of the C-rings with plate system 30.

The proper use of hinged plate system 30 is shown clearly in FIGS. 8-11. Referring now to FIG. 8, a bone graft 63, which replaces a removed vertebra, is inserted between vertebrae, and after the appropriate size of plate 32 has been selected, two bolts 50 are affixed within the appropriate vertebrae. Using openings 40 as a guide, a pair of holes are drilled into the vertebrae at a 15 degree anterior angulation, and bolts 50 are screwed into place through plate 32 to ensure that bolts 50 are placed in the proper location. The upper bolt 50 shown in FIG. 8 is preferably placed into the cephalad portion of opening 40 to allow for compression.

It is conceivable that other fastening systems could be used to secure plate 32 to the spine. For example, several two part screw systems having an outer

vertebral screw and a locking inner screw are taught in a patent application entitled ANATOMIC POSTERIOR LUMBAR PLATE, filed in the name of Bret A. Ferree on the same day as this application, and hereby incorporated by reference in its entirety, may be used in place of bolts 50 in the present invention, as these two part screws create a "bolt" as understood in relation to the present invention.

Next, posterior element 32b of plate 32 is flipped upwardly away from the vertebrae, as shown in FIG. 4, or plate 32 may be removed, and snap rings 60 are applied to upper threaded portion 54 of bolts 50 to secure them in place. Plate 32 is then repositioned over the two bolts 50 which have been secured in place within the vertebrae. Nut 62 is then tightened onto lower bolt 50, as can be seen in FIG. 10. The wrench used to tighten nut 62 onto lower bolt 50 is preferably cannulated to allow insertion of a screwdriver while tightening to prevent rotation of bolt 50 while nut 62 is threaded onto upper threaded portion 54 until it is tight against plate 32. While compressing graft material, which has been inserted between the vertebrae, nut 62 is placed upon upper threaded portion 54 of upper bolt 50 and securely tightened against plate 32.

Holes for bolts 50, which pass through openings 36, are now drilled using the openings as a drill guide (FIG. 10). Bolts 50 can then be affixed into place through element 32a of plate 32 (FIG. 11). Element 32a is then flipped upwardly, as can be seen in FIG. 12, and snap rings 60 are secured in place on upper threaded portion 54 of bolts 50. Element 32a of plate 32 can now be returned to its proper position against the vertebrae and nuts 62 are tightened to completely secure plate 32. Alternatively, openings 40 within element 32b may be beveled, as can be seen in FIG. 15, such that element 32a can be lifted slightly while located on upper threaded portion 54 of bolt 50 and snap ring 60 inserted below plate 32 onto bolt 50. This is

clearly seen in FIG. 15. Optionally, another screw 70 can be inserted through opening 42 into bone graft 63 (or a cage if it has been inserted).

FIG. 14 is a sectional view of a vertebra on which hinged plate system 30 has been installed. Bolts 50 can be seen penetrating the vertebra. The relative angularity between bolts 50 provides the proper force to securely hold plate system 30 in the proper orientation to promote healing. In addition, hinged section 34 assists to contour plate 32 to the convexity of the vertebrae, allowing plate 32 to more completely contact the vertebral surface.

Other modifications can be made to plate 32 in order to simplify the installation process. For example, FIG. 16 shows plate 32 where openings 40 in element 32a are slotted toward rounded edges 35a, 35b such that element 32a can be easily flipped upwardly.

An alternate embodiment of the spinal plate system of the present invention is shown in FIGS. 17-22. Referring now to FIGS. 17 and 18, a spinal plate system, as indicated at 100, is shown mounted in position on the spinal column of a patient. A unitary flat plate 102, having a plurality of slots 104a-e, is fastened at vertebrae 106, 108, in a fashion as previously described, by a plurality of bolts 110. A bone graft 112 is located between plate 102 and the spinal column. Plate 102 contains cutaway edge portions 113a, 113b to allow the surgeon to visualize the bone graft easily. Bolts 110, which are shown mounted through slots 104a-d, are held in place by a plurality of snap-rings 114. Central slot 104e located in the central region of plate 102 may be used for an additional screw or bolt through a central vertebra or bone graft. In addition, the bottom surface of plate 102 may contain a friction surface to allow better contact with the bone structures.

FIG. 19 shows a cross-sectional view of the plate of FIG. 17. Plate 102, which is approximately 7 mm in thickness, is curved to allow for better contact with the vertebral surface. Also, anterior slot 104a, which is approximately 7 mm in width, lies perpendicular to the upper and lower surfaces of plate 102, while posterior slot 104b, also approximately 7 mm in width, is angled approximately 15° anteriorly. The range of lengths available for plate 102 are from 60 mm to 110 mm, while the width across plate 102 at its widest portion is approximately 20mm. The width across cutaway sections 112a, 112b is approximately 12 mm.

Plate 102 can be shaped to more easily fit the spinal shape when used in different areas. FIG. 20 shows plate 102 which is angled 15° in the forward direction to compensate for kyphotic conditions, while FIG. 21 shows plate 102 which is angled 15° in the reverse direction to compensate for lordotic conditions. Finally, a shorter plate 102 is shown in FIG. 22, which may be used in situations where longer plates cannot be used or are not necessary.

While the present invention has been shown and described in terms of preferred embodiments thereof, it will be understood that this invention is not limited to any particular embodiment, and that changes and modifications may be made without departing from the true spirit and scope of the invention as defined in the appended claims.

What is claimed is:

1) A device for rigidly affixing vertebrae of a spine, comprising:

A flat plate comprising a first plate section having a first pair of collinear through openings and a second plate section, hingedly affixed to said first section, having a second pair of collinear through openings, with said first and second pairs of openings capable of receiving bone engaging screws for affixing said plate to vertebrae of a spine.

2) The device of claim 1, wherein said first pair of openings comprise slots elongated along a longitudinal axis through said openings.

3) The device of claim 1, wherein said second pair of comprise slots elongated along a longitudinal axis through said openings.

4) The device of claim 1, wherein said openings through said second plate section lie at a 15° anterior angulation.

5) The device of claim 1, wherein said plate is manufactured from titanium.

6) The device of claim 1, further comprising a third opening comprised of a first cutout section from said first plate section and a second cutout section from said second plate section.

7) The device of claim 1, wherein said first pair of openings extend perpendicularly from said second plate section to the outer edge of said first plate section.

8) A system for fixation of the spine, comprising;

a flat plate comprising a first plate section having a first pair of through openings, and a second plate section having a second pair of through openings;

a plurality of bone engaging screws, one for each of said through openings, with each of said screws including a lower threaded section for affixing said screw within bone, a central unthreaded section, and an upper threaded section;

and a plurality of nuts capable of threadedly engaging said upper threaded section of said screws.

9) The system of claim 9, further including a plurality of locking devices capable of which may be fixed in position on said lower threaded portion of said screws.

10) The system of claim 9, further including a hinge section coupling said first and second plate sections.

11) The system of claim 9, wherein said second pair of through holes lie at a 15° anterior angulation to the upper surface of said second plate section.

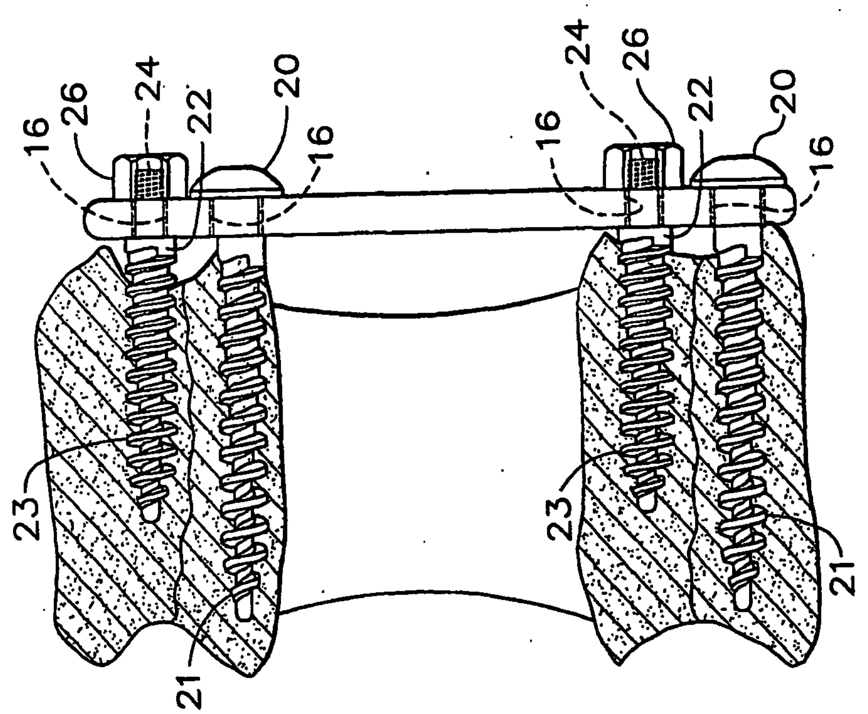
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FIG. 2

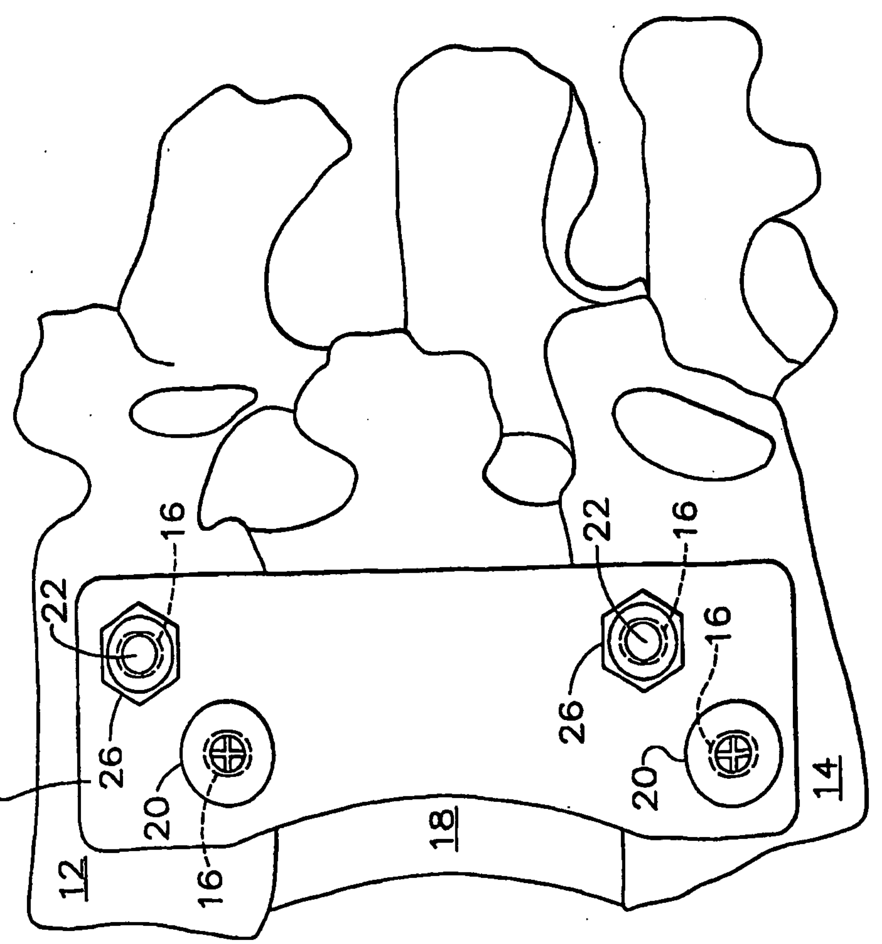
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FIG. 1

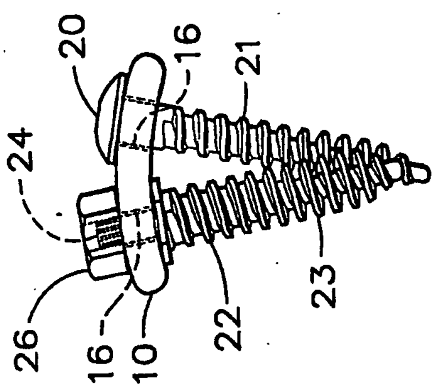


FIG. 4

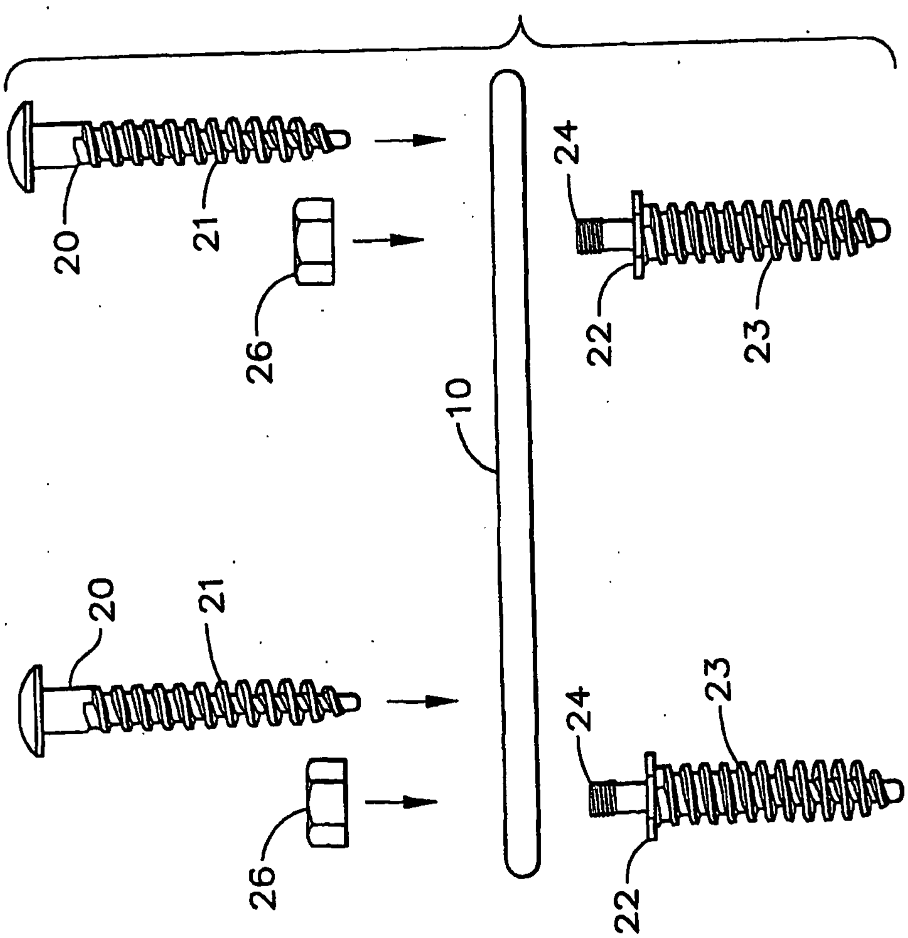
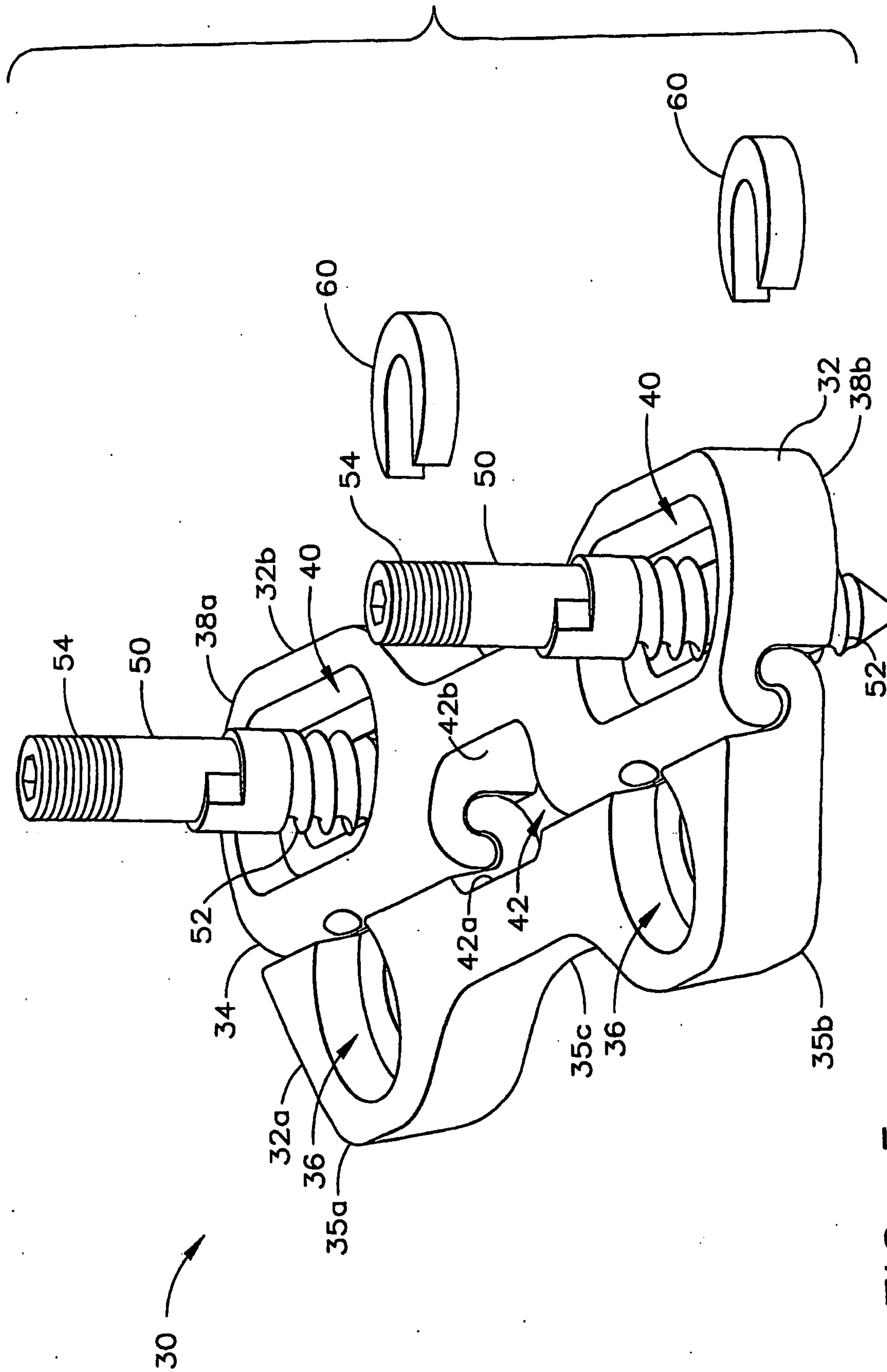


FIG. 3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35c
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35b
32a
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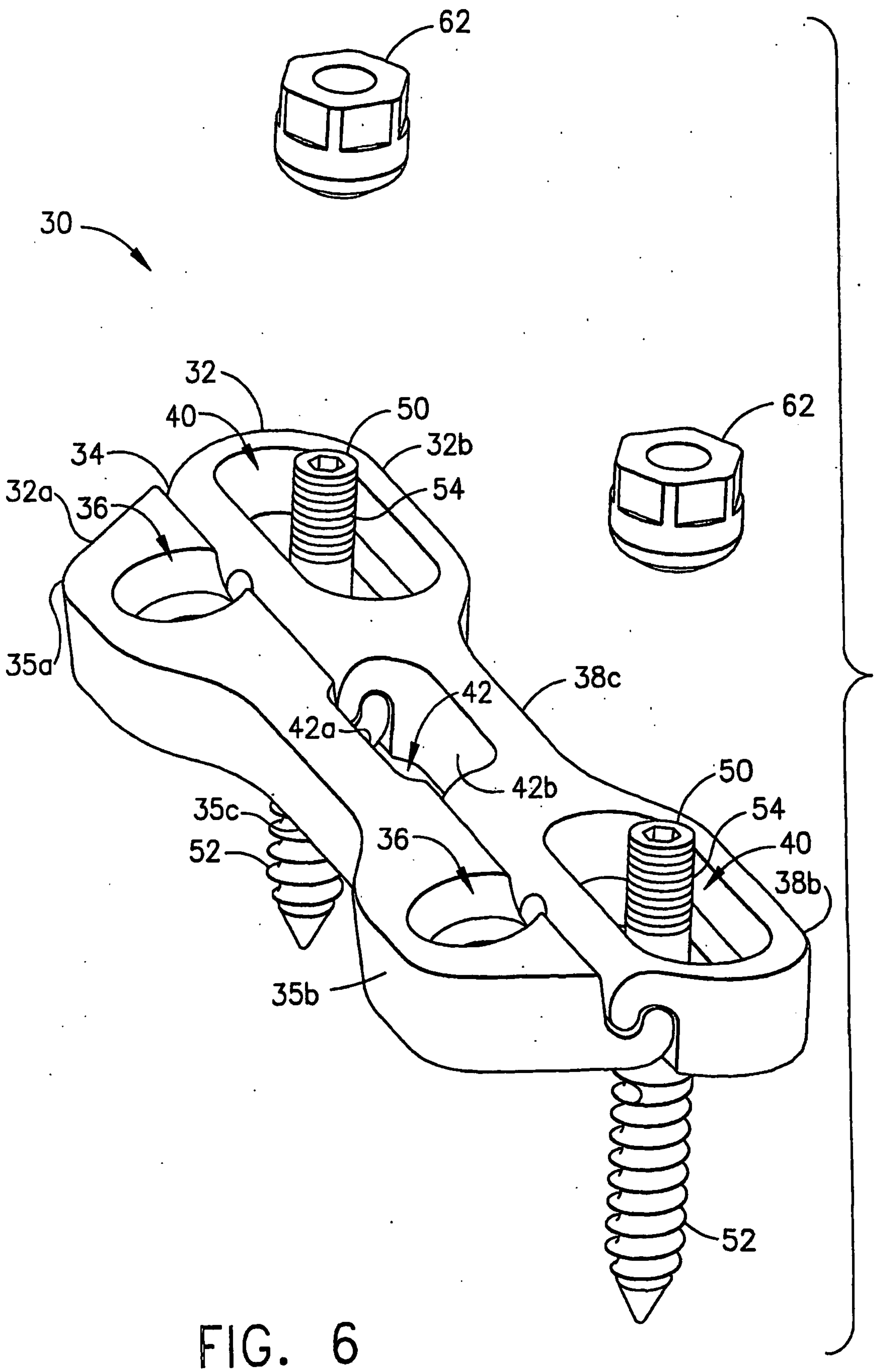
35a
30

FIG. 5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35b
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FIG. 6

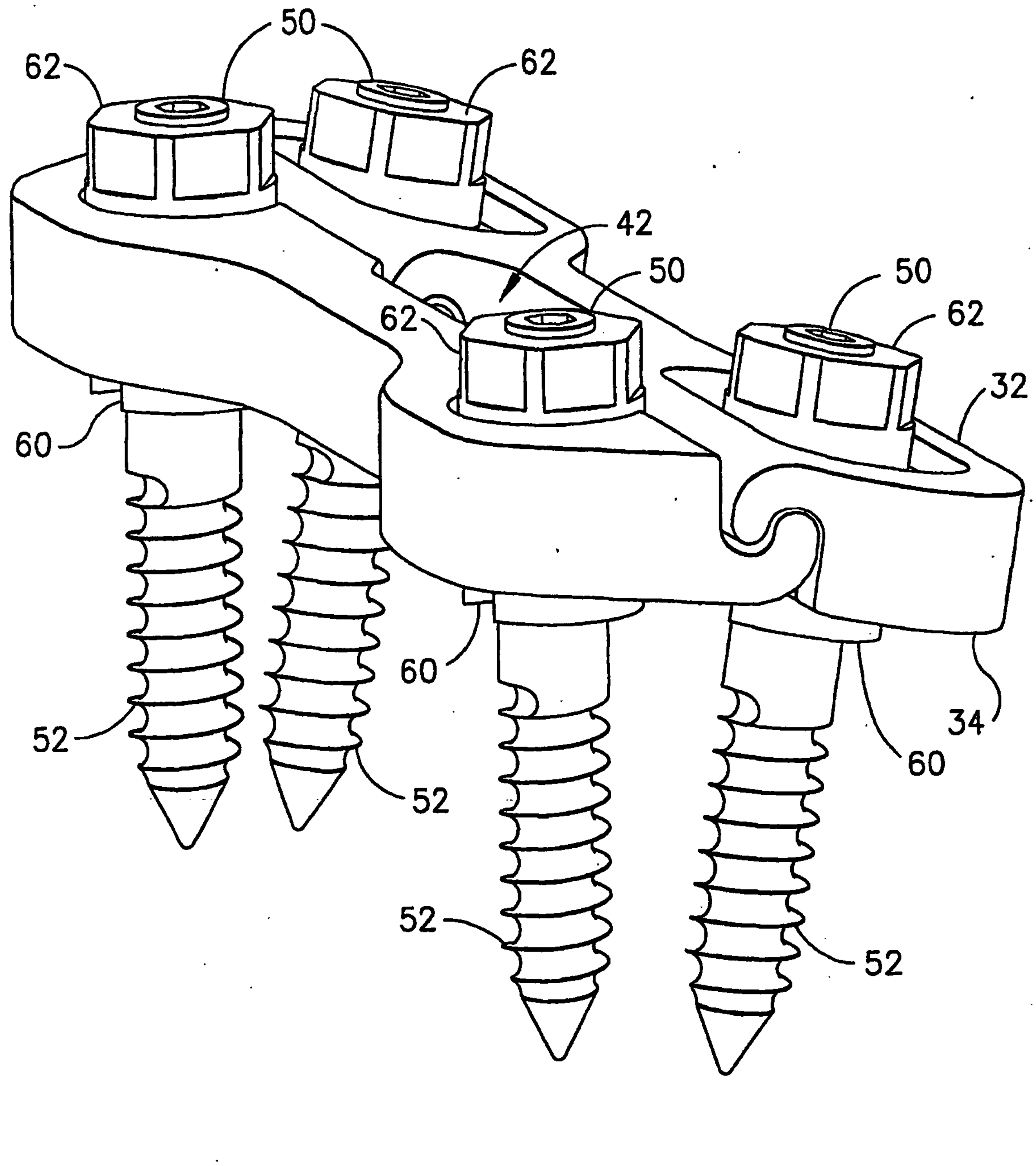

FIG. 7

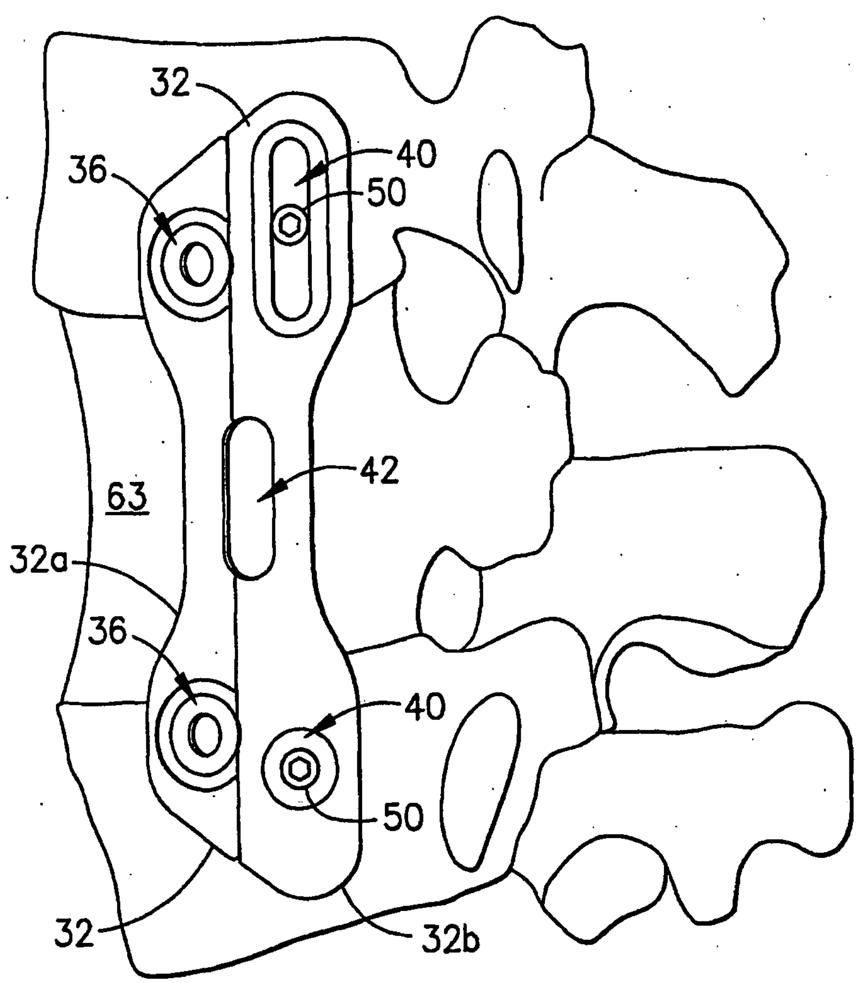

FIG. 8

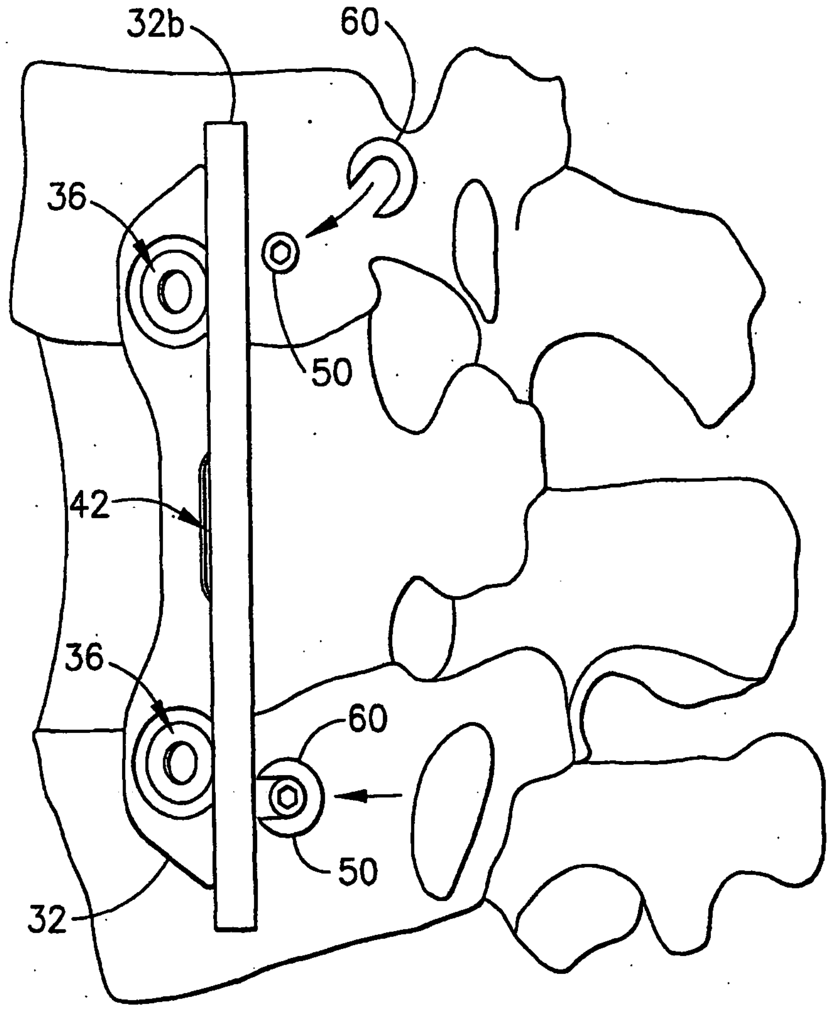

FIG. 9

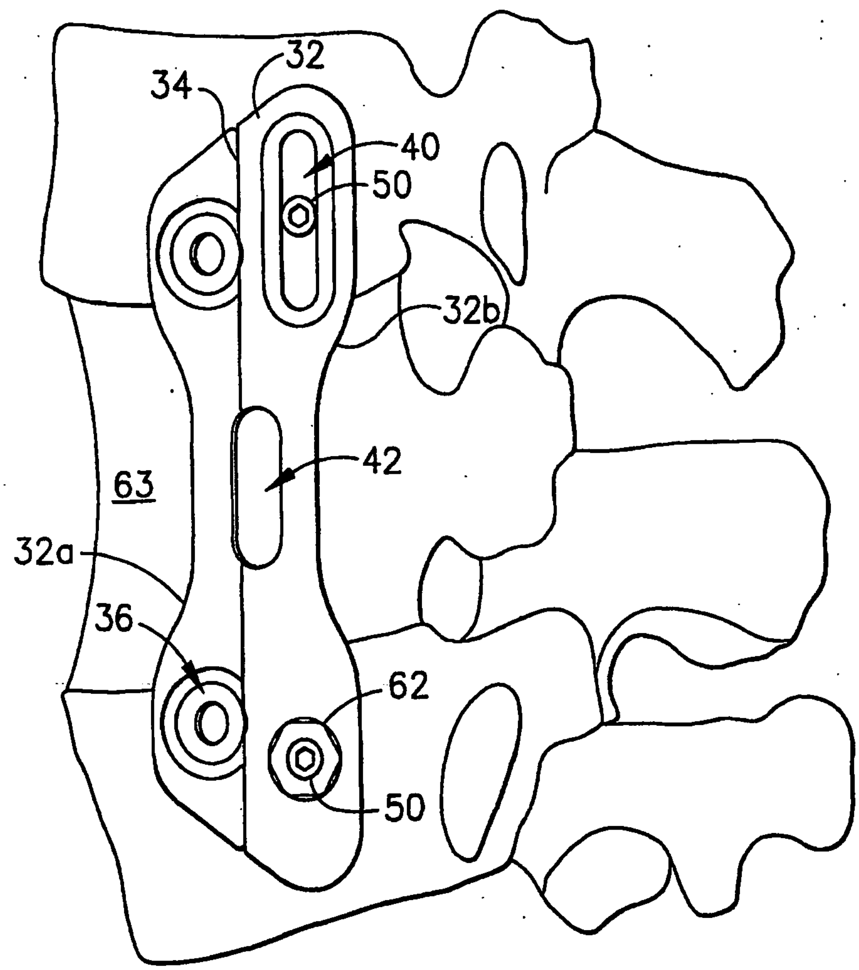

FIG. 10

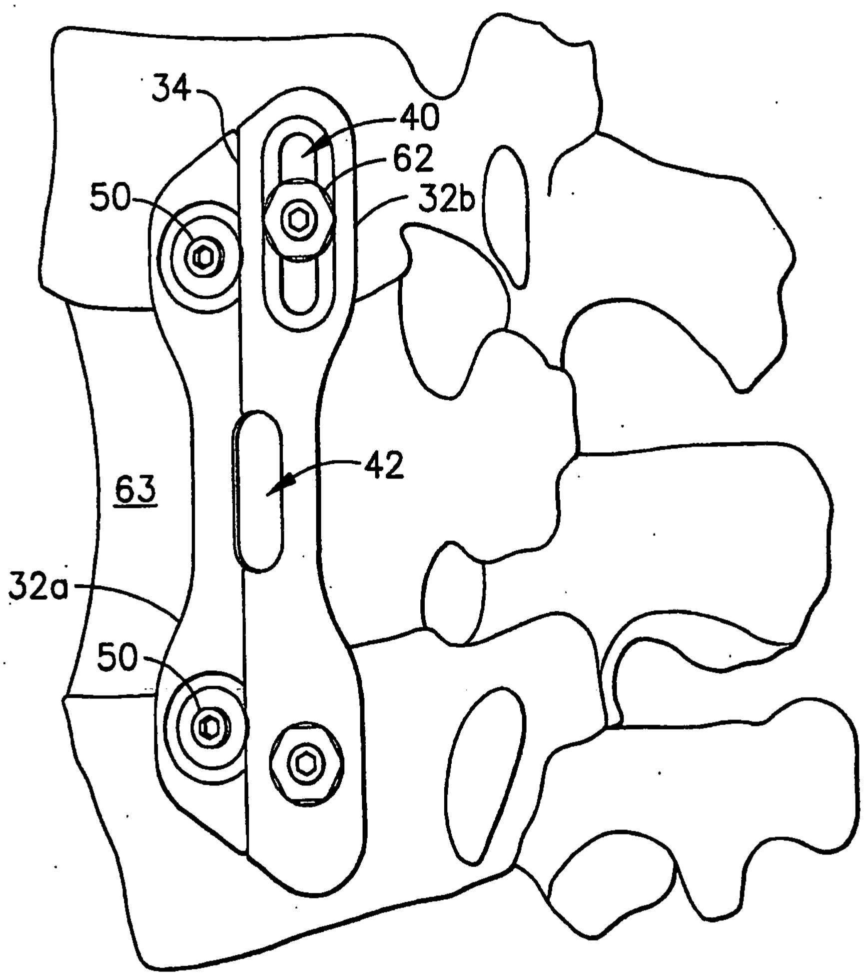

FIG. 11

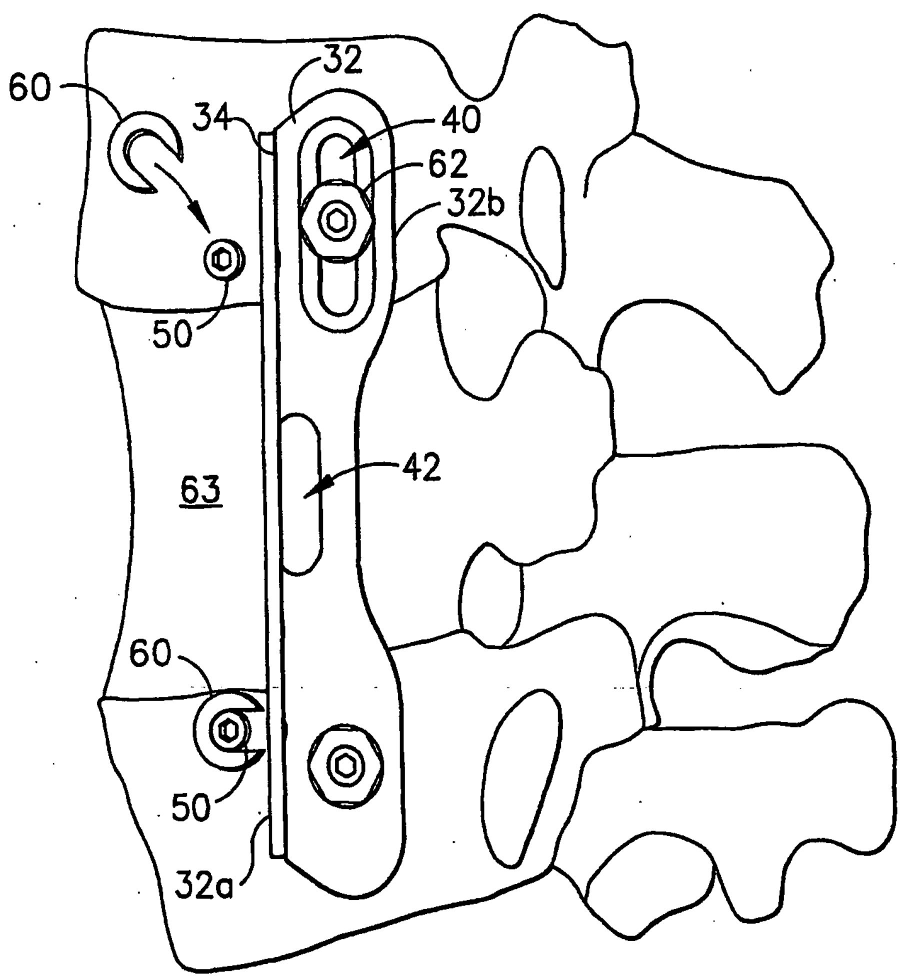

FIG. 12

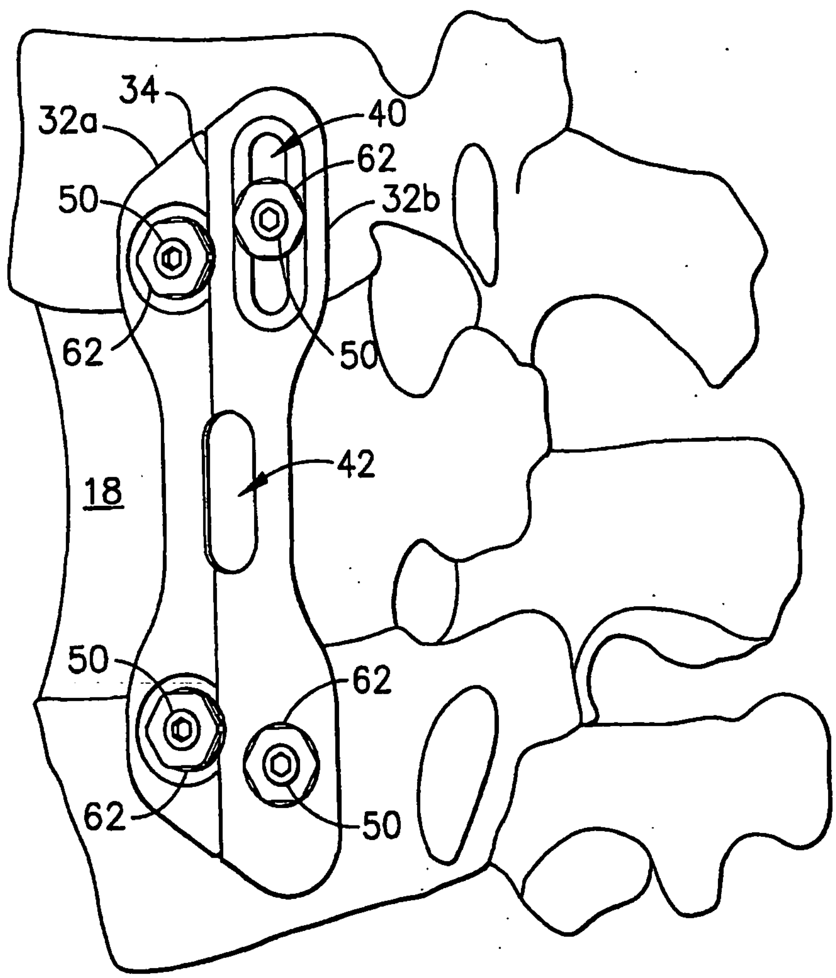

FIG. 13

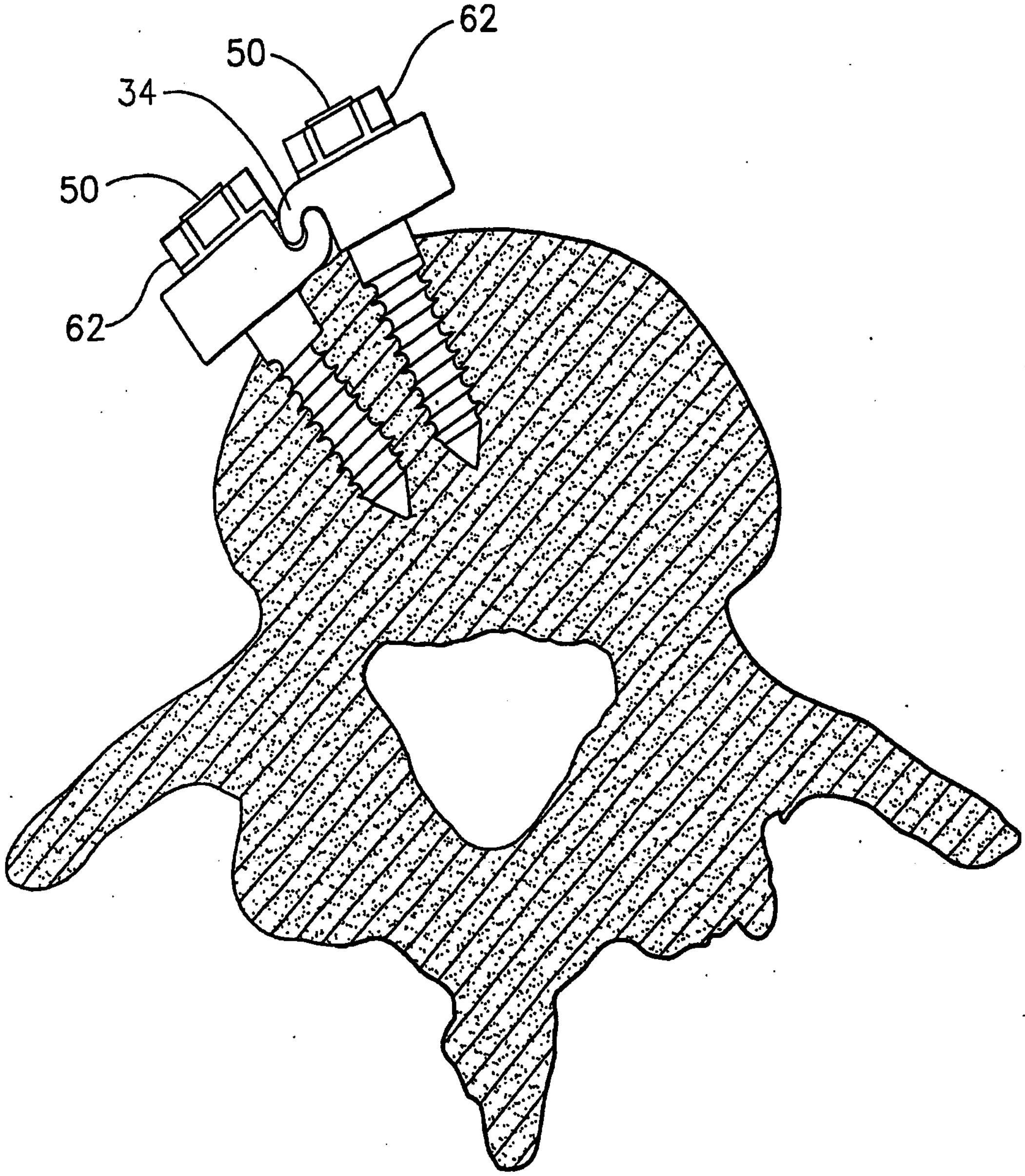

FIG. 14

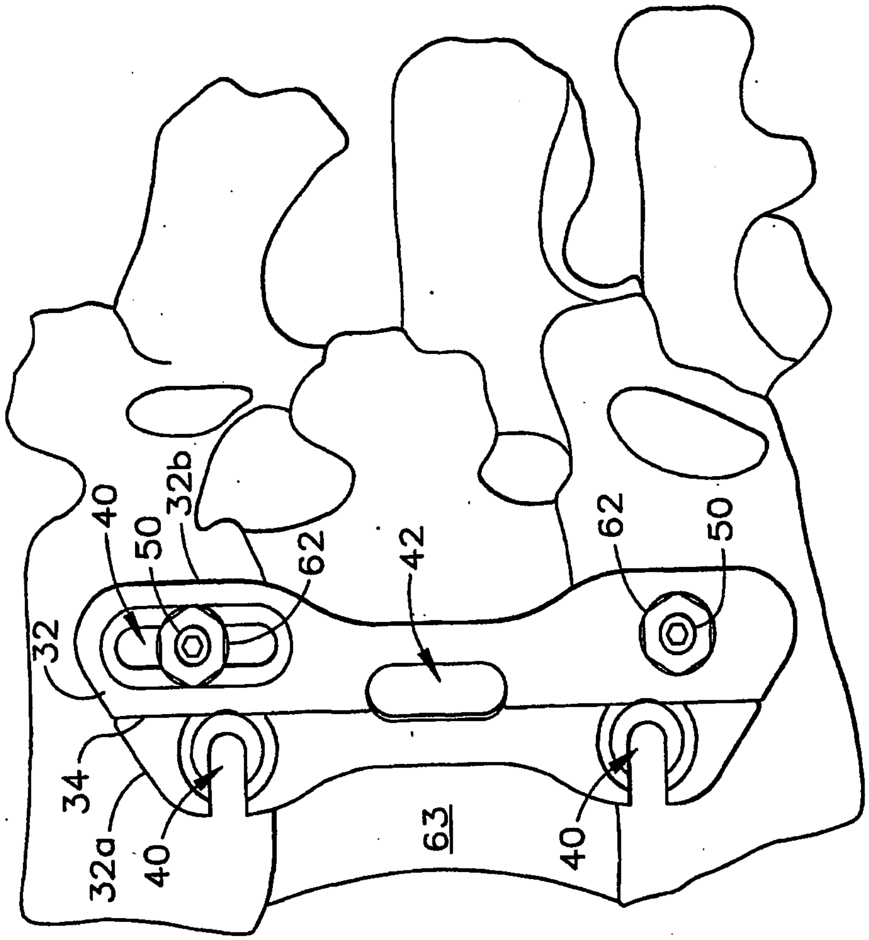

FIG. 16

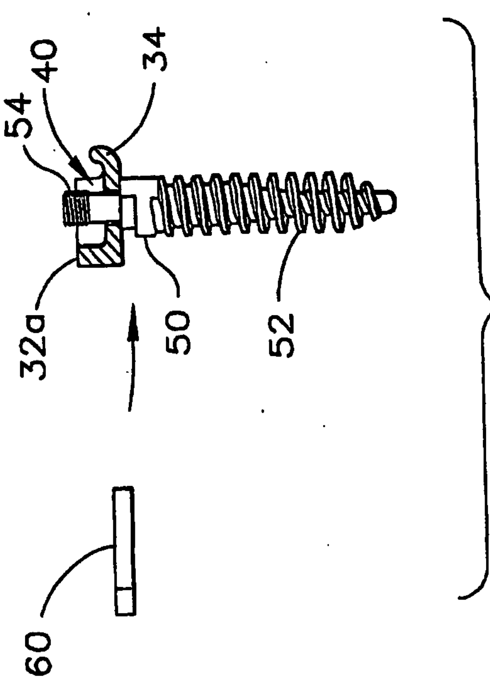

FIG. 15

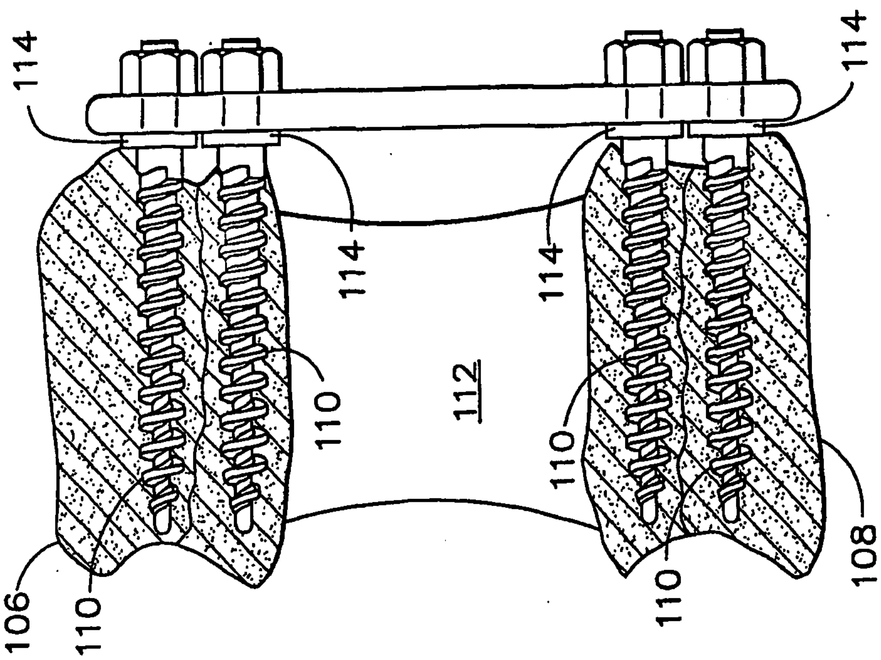
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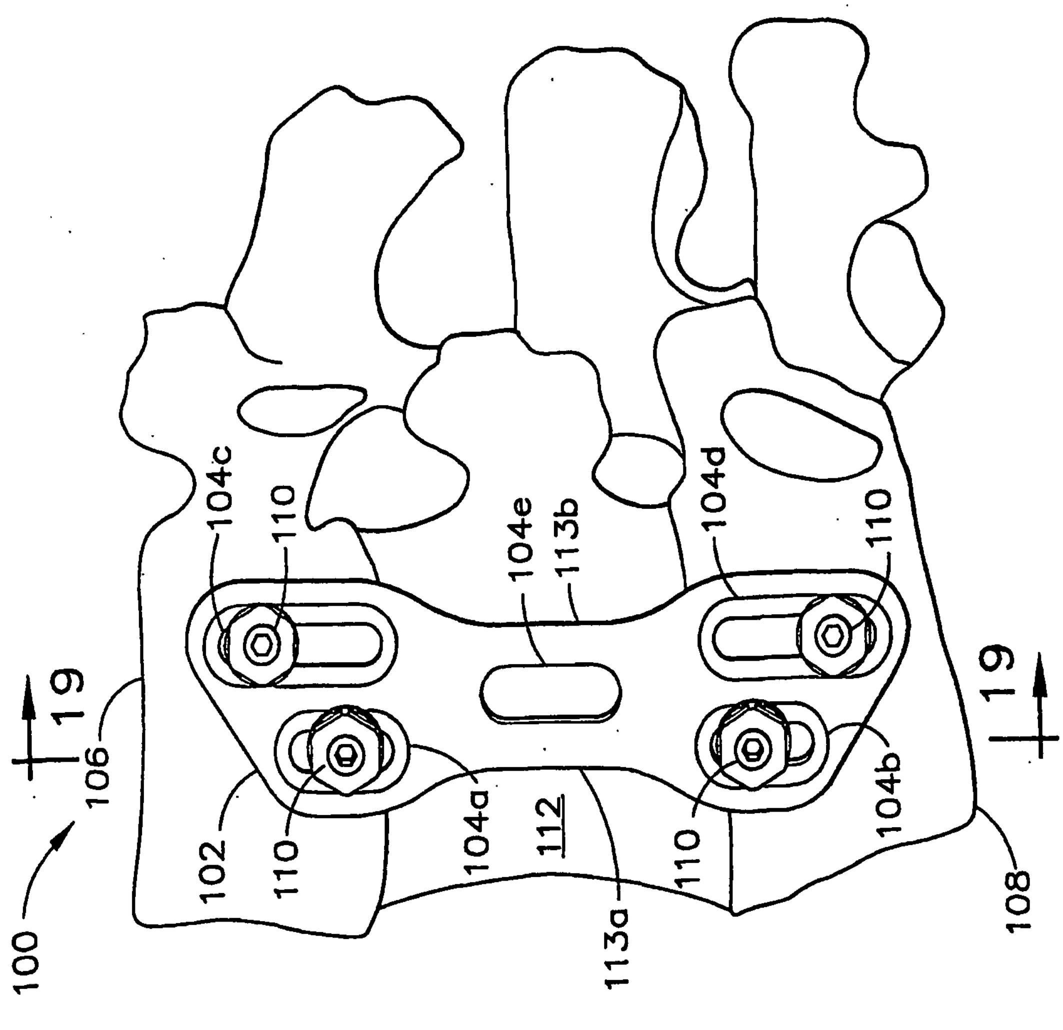
FIG. 18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104c
104d
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110
110
110
110
112
113a
113b
19
19

FIG. 17

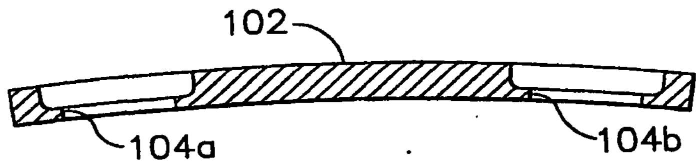

FIG. 19

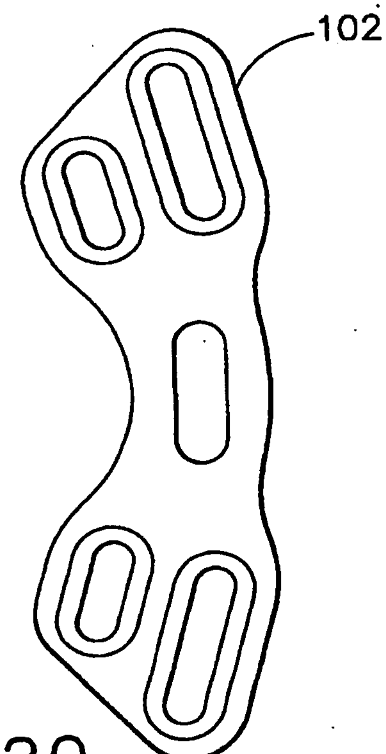

FIG. 20

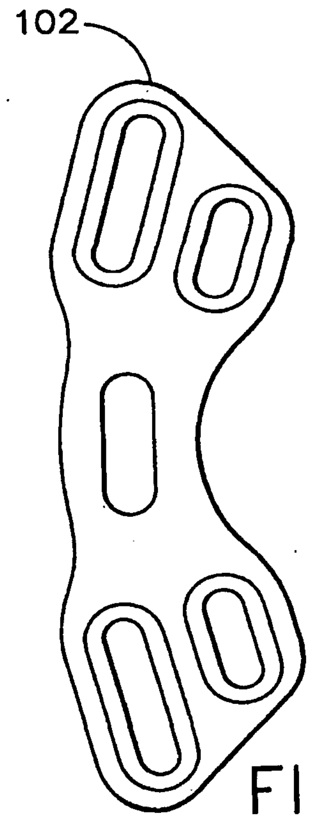

FIG. 21

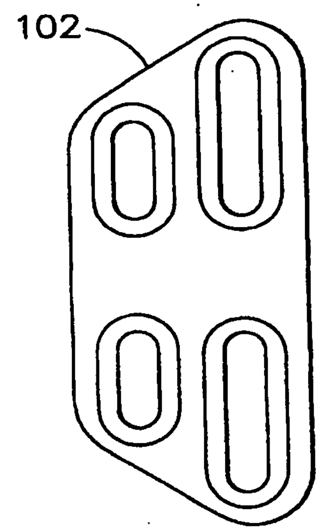

FIG. 22

INTERNATIONAL SEARCH REPORT

Internation[redacted]plication No
PCT/US 02/09168

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/70 A61B17/80

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 97 22306 A (SMITH & NEPHEW INC) 26 June 1997 (1997-06-26) the whole document ---	1
A	DE 92 19 204 U (ULRICH HEINRICH) 16 December 1999 (1999-12-16) the whole document ---	1
A	US 6 030 389 A (WAGNER ERIK J ET AL) 29 February 2000 (2000-02-29) the whole document ---	1
A	US 5 954 722 A (BONO FRANK S) 21 September 1999 (1999-09-21) the whole document ----	1

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

12 July 2002

Date of mailing of the international search report

19/07/2002

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INTERNATIONAL SEARCH REPORT

Information on patent family members

Internation[redacted]plication No

PCT/US 02/09168

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			WO	9905968	A1	11-02-1999